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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,219	11/19/2001	Brian J. Stockman	6283NCP2	9179

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT PAPER NUMBER


1639

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/044,219	Applicant(s) Stockman et al
Examiner Maurie G. Baker, Ph.D.	Art Unit 1639



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Aug 19, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 46-53 and 55 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 46-53 and 55 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) Other:

DETAILED ACTION

1. The Response filed August 19, 2003 (Paper No. 12) is acknowledged. Claims 46, 47 and 53 were amended, claims 1-45 and 54 were cancelled and no claims were added. Therefore, claims 46-53 and 55 are pending and under examination.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The instant application is a continuation-in-part of application 09/677,107, which claims priority to provisional applications 60/516,818, 60/161,682 and 60/192,685.

However, all of the provisional applications upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for the *full scope* of the claims of this application since they do not contain a reference to WaterLOGSY NMR. Note that a broad generic disclosure is **not** sufficient support for a specific entity within the class. Thus, claims 46-55 are only awarded the filing date of application 09/677,107, which is 9/29/00.

Response to Arguments

3. Applicant's statements filed August 19, 2003 have been fully considered. Applicant admits that provisional applications 60/516,818, 60/161,682 and 60/192,685 do not specifically

refer to WaterLOGSY NMR but have not deleted their priority claim. Thus the priority claim continues to be denied for the reasons set forth above.

Status of Objections & Rejections

4. The objections to the instant specification and to claims 47 and 55 are withdrawn in view of applicant's amendments thereto. The rejection of claims 46 and 53 under 35 U.S.C. 112, first paragraph for new matter is withdrawn in view of applicant's amendments to the claims. The rejection of claim 54 under 35 U.S.C. 112, first paragraph for lack of enablement is withdrawn in view of the cancellation of the claim. The rejections under 35 U.S.C. 112, second paragraph for new matter are withdrawn in view of applicant's amendments to/cancellation of claims. The rejection under 35 U.S.C. 103(a) is maintained and applicant's arguments are addressed following the rejection.

***Maintained Rejections
Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the t

ime any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 46-53 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dalvit et al, (J. Biomol. NMR, 2000; on PTO-1449) in view of Keifer et al (J. Combi. Chem. 2000; on PTO-1449).

It is noted that the Dalvit reference was published in September 2000, but at the bottom of page 65 it is stated that the work in the article was presented at a conference on February 19, 2000. Also, applicants cite this article on page 14, lines 3-4 of the instant specification.

Dalvit et al teach a “powerful screening by NMR methodology (WaterLOGSY)” (see Abstract). In fact, Dalvit et al coin the term WaterLOGSY on page 67, 2nd column. A mixture of “10 low molecular weight compounds (concentration 100 μ M)” in the presence of 10 μ M of protein is tested for compound binding (page 67, 2nd column and Figure 1). This reads on the limitations of claims 47, 49, 50, 52, 53 and 55. The WaterLOGSY NMR spectra are compared with a reference spectrum (see Figure 2 and accompanying text, especially page 68, 1st column, top). Both 1D and 2D WaterLOGSY spectra are taken (pages 67-68), reading on instant claim 51. The compounds of the mixture of Dalvit have NMR signals “consisting mostly of sharp singlets”, reading on

claim 52. The solubility (instant claim 50) and dissociation constant are intrinsic features of a compound and thus are deemed to be taught by the compounds tested in the method of Dalvit et al, absent evidence to the contrary. Also, the reference teaches “the sensitivity of the method to protein concentrations as low as a few hundred nM” (page 68, 1st column), reading on the limitations of claims 48.

The reference lacks the teaching of a “plurality of mixtures of test compounds” and using a flow-injection probe.

However, the use of such apparatus and methodology was well established in the art of high-throughput testing/combinatorial chemistry at the time of filing, see for example, Keifer et al. See the entire teachings of the reference, specifically Abstract and pages 151 & 153 for teachings of the use of flow probes and 96-well plates in a flow NMR technique for the analysis of combinatorial chemistry libraries. The techniques of Keifer et al are specifically for testing libraries, and mixture analysis is also taught (see page 167). This would read on the “plurality of mixtures of test compounds”.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to carry out the method of Dalvit et al using a “plurality of mixtures of test compounds” and a flow-injection probe as these are standard in the art as evidenced by Keifer et al. One of ordinary skill would have been motivated to do so due in order to have the advantageous sample handling capacity of Keifer et al and to more easily automate the screening of libraries (see pages 151-152 of Keifer et al for the advantages of their technique).

Response to Arguments

8. Applicant's arguments filed August 19, 2003 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

9. Applicant argues that there is "no teaching or suggestion in either document of the use of the WaterLOGSY NMR method to identify the function of a target molecule, such as a protein, using a mixture of test compounds consisting of known inhibitors, cofactors and substrates of known proteins" (Response, page 13). Although this teaching is not explicitly set forth in the Dalvit reference, it is the examiner's position that such would be implicit from the disclosure of the reference. See MPEP 2144.01: "[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom." *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968). Moreover, as there is currently no requirement in the claim that the target molecule have an unknown function (see next paragraph), and the mixture of 10 low molecular weight compounds used in the reference to test for binding with cdk2 clearly are known inhibitors, cofactors and substrates of known proteins, the disclosure of the Dalvit reference reads on the instant claims.

10. Also, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., starting with a target molecule of unknown function) are not recited in the rejected claim(s). Although

the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

11. For these reasons and the reasons of record, the above rejection under 35 U.S.C. 103(a) is maintained.

Status of Claims/Conclusion

12. No claims are allowed.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703)

308-0065. The examiner is on an increased flextime schedule but can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

15. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
October 30, 2003



**MAURIE GARCIA BAKER PH.D.
PRIMARY EXAMINER**